



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,708	08/22/2001	Thomas Piccariello	54719.000028	6976

7590 07/06/2005

Robert M. Schulman, Esq.
Hunton & Williams
Suite 1200
1900 K Street, N.W.
Washington, DC 20006-1100

EXAMINER

RUSSEL, JEFFREY E

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/933,708	Applicant(s) PICCARIELLO ET AL.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,13,14,17,20,22-33,75,76 and 135-194 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,13,14,17,20 and 22-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75,76 and 135-194 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

500

Art Unit: 1654

1. Applicant's election with traverse of the species zidovudine in the Paper filed January 5, 2004 is acknowledged. The requirement is still deemed proper and is therefore made FINAL.

Claims 3, 4, 13, 14, 17, 20, and 22-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the Paper filed January 5, 2004.

This application contains claims 3, 4, 13, 14, 17, 20, and 22-33 drawn to an invention nonelected with traverse in Paper No. filed January 5, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

(a) An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Note that the declaration filed on January 11, 2002 refers to U.S. non-provisional application 09/642,820, but this application is not mentioned in the claim for priority contained in the preliminary amendment filed December 26, 2001.

Art Unit: 1654

(b) The claim for priority contained in the preliminary amendment filed December 26, 2001, uses the language “is a continuation in part of”, to claim priority based upon numerous provisional applications. The language “is a continuation in part of” is language typically used to claim priority under 35 U.S.C. 120. While it is permitted to claim priority under 35 U.S.C. 120 based upon a provisional application, Applicants may not have intended to do so because this may have the effect of reducing the patent term of any patent which issues based upon this application. See MPEP 201.11(III)(B). Further, this language in the priority claim inserted into the specification contradicts the priority claim language in Applicants’ Request For Corrected Filing Receipt filed January 11, 2002, which uses the language “claims priority of” and is language typically used to claim priority under 35 U.S.C. 119(e).

(c) Applicants need to review their priority claims, and need either to affirm that the priority claim contained in the preliminary amendment filed December 26, 2001 is the intended priority claim, or to submit a further amendment correcting the priority claim.

Note that any amendment to the priority claim will require a petition under 37 CFR 1.78(a). If the application is an application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a nonprovisional application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the reference to the prior application must be made during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months

Art Unit: 1654

from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). If applicant desires priority under 35 U.S.C. 120 or 119(e) based upon a previously filed application, applicant must file a petition for an unintentionally delayed benefit claim under 37 CFR 1.78(a)(3) or (a)(6). The petition must be accompanied by: (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted); (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Applicants' amendment and petition with respect to the priority claim was received on June 17, 2004. The examiner has been in regular contact with the Office of Petitions since November 2004 but has been unable to determine when the petition will be decided.

3. At amended claim 76, line 5, "nevirapine," is both struck-through and underlined. The claim will be interpreted as though the word has been deleted from the claim.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 135-138, 141-166, and 169-194 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

Art Unit: 1654

possession of the claimed invention. Claims 135-138, 141-166, and 169-190 embrace compositions in which zidovudine is attached to a single amino acid. However, the only disclosure in the specification of active agents being attached to a single amino acid occurs at page 6, line to page 7, line 19, and at Example 13, in which an active agent is attached to the side chain of an amino acid which is used as a reaction intermediate to form a polypeptide comprising the attached active agents. None of the current claims are drawn to such side chain attachment. The original disclosure of the invention (see, e.g., page 1, lines 5-7; page 4, lines 6-7; page 9, lines 9-10; and the originally-filed claims) requires attachment of the active agent to a polypeptide, and the instant claims do not contain such a requirement. There is no original disclosure supporting the recitation in claims 191-194 of the specific combinations of amino acids where zidovudine is attached to the carboxyl or amine group of glutamic acid or of lysine. Polypeptides comprising specific combinations of amino acids, other than for homopolymers of certain amino acids, are not disclosed in the specification. Applicants cite to several sections of the specification as support for the new claims (see the "Remarks" section of the response); however, none of these cited sections mention combinations of glutamic acid with arginine, glutamic acid with glutamine, glutamic acid with phenylalanine, etc. See, e.g., MPEP 2163.05(II) and *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species).

5. Claims 191 and 194 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Art Unit: 1654

applicant regards as the invention. Claim 191 is indefinite because it is unclear if the claim is requiring that zidovudine be attached to the carboxyl group which is present in the side chain of glutamic acid or which is present at the C-terminus of glutamic acid. Claim 194 is indefinite because it is unclear if the claim is requiring that zidovudine be attached to the amine group which is present in the side chain of lysine or which is present at the N-terminus of lysine.

6. Claims 136, 138-162, 164, and 166-194 are objected to because of the following informalities: At claims 136, 138, 164, 166, 192, and 194, line 2 of each claim, "amine" is misspelled. In claims 141-162 and 167-190, "naturally occurring" should be deleted from each claim so that claim terminology is consistent with that used in the independent claims. In claims 191-194, line 4 of each claim, a comma should be inserted after "threonine". Appropriate correction is required.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1654

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976); *In re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 98/04277. The WO Patent Application '277 teaches a prodrug of the formula recited at page 6, lines 1-21, in which a therapeutic agent, in particular AraC, didanosine, zidovudine, and stavudine, is attached via its amine group to the C-terminus of a peptide having from 2 to eleven amino acids. The amino acids in the peptide can be synthetic, and are chosen to control the rate of cleavage of the peptide from the therapeutic agent. In compound 19, the peptide is comprised of two different synthetic amino acids, Aib and Azagly, which peptide corresponds to Applicants' heteropolymer of two or more synthetic amino acids. The prodrugs can be administered orally. The WO Patent Application '277 also teaches attachment of the

Art Unit: 1654

peptide to the therapeutic agent through a reactive hydroxyl function of the therapeutic agent.

See, e.g., page 3, line 24 - page 4, line 2; page 6, lines 17-21; page 7, lines 19-21; page 7, line 29 - page 8, line 7; page 12, lines 17-19; page 15, lines 8-11; and page 16, lines 7-10. AraC, didanosine, zidovudine, and stavudine are antiviral agents.

9. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (U.S. Patent No. 5,534,496). Lee et al teach drugs which are covalently attached to a peptide. The drugs can be acyclovir and ganciclovir, which are antiviral agents. See, e.g., claims 1 and 7.
10. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Fiume et al (U.S. Patent No. 5,594,110). Fiume et al teach AZT covalently conjugated to lactosaminated human albumin. See, e.g., claims 1 and 2. Albumin is a polypeptide.
11. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Yatvin et al (U.S. Patent No. 5,965,519). Yatvin et al teach AZT covalently conjugated through a phosphate group to tetraglycine. See, e.g., Figure 8.
12. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Simon et al (U.S. Patent No. 5,965,695). Simon et al teach AZT covalently bound to a peptoid comprising 2 to 50 N-substituted glycine residues. See, e.g., claims 1 and 8.
13. Claim 75 is rejected under 35 U.S.C. 102(b) as being anticipated by Josephson et al (U.S. Patent No. 5,981,507). Josephson et al teach araA conjugated to polyglutamic acid. See, e.g., Table 1 and Example 35. AraA, i.e. vidarabine, is an antiviral agent.
14. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by the Giammona et al article (J. Controlled Release, Vol. 54, pages 321-331). The Giammona et al

Art Unit: 1654

article teaches zidovudine covalently conjugated to polyaspartamide. See, e.g., the Abstract and Scheme II, compound 4.

15. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by the Hussain et al article (Liebigs Ann. Chem., 1992, pages 169-171). The Hussain et al article teach AZT covalently conjugated to polypeptides comprised of lipidic amino acids. See, e.g., the abstract and page 169, column 1, compounds 3b-3e.

16. Claims 75, 76, 135, 139, 142, 163, 167, and 170 are rejected under 35 U.S.C. 102(b) as being anticipated by the Matsumoto et al article (Bioorganic & Medicinal Chemistry Letters, Vol. 10, pages 1227-1231). The Matsumoto et al article teaches AZT conjugated to a dipeptide comprising two different non-natural amino acids. See, e.g., Figure 4, Scheme 1, and Table 1. Also, for compounds 4a and 4b of Table 1, the reference teaches zidovudine conjugated through its hydroxyl group directly to the carboxyl group of a glycine residue. The compounds are dissolved in PBS (see page 1229, column 2, third full paragraph). An aqueous solution is capable of being administered orally, even though it may not be intended to be administered orally. An intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art. Because of the identity in structure between the compounds of the Matsumoto et al article and Applicants' claimed compositions, the compounds of the Matsumoto et al article will inherently release the zidovudine into the bloodstream following oral administration to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the compounds of the Matsumoto et al article and Applicants' claimed compositions to shift the burden to Applicants to provide evidence that the

Art Unit: 1654

claimed compositions are unobviously different than the compounds of the Matsumoto et al article.

17. Claims 75, 76, 135, 139-141, 163, and 167-169 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Bahr et al (U.S. Patent No. 6,267,968). Bahr et al teach AZT conjugated through its hydroxyl group to the C-terminus of alanine. Further reaction causes the C-terminus to be directly attached to D-Glu, and indirectly to L-Ala. The first compound is produced in dry powder form, and the latter compound is produced in aqueous solution and in dry powder form, all of which are orally administratable. See Example 11. Because of the identity in structure between the compounds of Bahr et al and Applicants' claimed compounds, inherently the compounds of Bahr et al will be capable of enzymatically releasing the AZT to the bloodstream following oral administration to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the compounds of Bahr et al and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that the claimed compounds are unobviously different than those of Bahr et al.

18. Claims 75, 76, 135, 137, 142, 146, 163, 165, 170, and 174 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 96/25147. The WO Patent Application '147 teaches AZT conjugated through its hydroxyl group to the C-terminus of amino acids, such as Phe and Gly. The conjugates are then formulated into liposomes. See, e.g., page 9, lines 4-9; Example 1A and B; Table I; and claims 1 and 3. Liposomes are orally administratable forms. Because of the identity in structure between the conjugates of the WO Patent Application '147 and Applicants' claimed compounds, inherently the compounds of the WO Patent Application '147 will be capable of enzymatically releasing the AZT to the

Art Unit: 1654

bloodstream following oral administration to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the conjugates of the WO Patent Application '147 and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that the claimed compounds are unobviously different than those of the WO Patent Application '147.

19. Claims 135, 137, 141, 143-145, 147-151, 163, 165, 171-173, and 175-179 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 96/25147. Application of the WO Patent Application '147 is the same as in the above rejection of claims 75, 76, 135, 137, 142, 146, 163, 165, 170, and 174. The WO Patent Application '147 teaches conjugating AZT to amino acids in general (see, e.g., page 6, lines 19-24), but does not specifically teach conjugating AZT to Ala, Leu, Ile, Val, Pro, Asp, Ser, Thr, or Tyr. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to conjugate AZT to Ala, Leu, Ile, Val, Pro, Asp, Ser, Thr, or Tyr because these amino acids are generically encompassed by the WO Patent Application '147, because these amino acids are naturally occurring and among the most common amino acids, and because the resulting conjugates would still have been expected to be administratable in the form of liposomes as is desired by the WO Patent Application '147.

20. Claims 75, 76, 135, 137, 144, 146, 151, 163, 165, 172, 174, and 179 are rejected under 35 U.S.C. 102(b) as being anticipated by the Aggarwal et al article (J. Med. Chem., Vol. 33, pages 1505-1510). The Aggarwal et al article teaches AZT conjugated through its hydroxyl group to the carboxyl terminus of Phe, Tyr, and Ile. The compounds are dissolved in phosphate buffer. See Table I and page 1509, column 2, fourth full paragraph. Phosphate buffer solutions are

Art Unit: 1654

orally administratable forms. Because of the identity in structure between the compounds of the Aggarwal et al article and Applicants' claimed compounds, inherently the compounds of the Aggarwal et al article will be capable of enzymatically releasing the AZT to the bloodstream following oral administration to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the conjugates of the Aggarwal et al article and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that the claimed compounds are unobviously different than those of the Aggarwal et al article.

21. Applicant's arguments filed August 11, 2004 have been fully considered but they are not persuasive.

In the first Office action on the merits, claims 75 and 76 were rejected on the basis of anticipation over several prior art references. Applicants did not submit any amendments to claim 75, and only amended claim 76 with respect to certain of the non-elected species. Accordingly, claims 75 and 76 will continue to be rejected over the same prior art references, because the differences argued by Applicants in their remarks are not recited in either of these two claims. For example, with respect to claims 75 and 76 and the WO Patent Application 98/04277, Applicants contend that "[t]he claimed invention is not attached through zidovudine's amine group". However, claims 75 and 76 are silent as to where zidovudine might be attached to the polypeptide, and embrace zidovudine attached through its amine group to the polypeptide. Patentability must be based upon claimed, not unclaimed, differences over the prior art.

Generic claims 75 and 76 embrace antiviral agents which are acyclovir and ganciclovir, and thus will continue to be rejected over Lee et al (U.S. Patent No. 5,534,496). It is standard Office practice to reject generic claims on any appropriate basis regardless of the elected species-

Art Unit: 1654

otherwise it is not possible to determine whether a generic claim is allowable and whether the search and examination should be extended to nonelected species. The election of species requirement will not be withdrawn.

With respect to the rejection over the Matsumoto et al article (Bioorganic & Medicinal Chemistry Letters, Vol. 10, pages 1227-1231), for compounds 4a and 4b of Table 1, the reference teaches zidovudine conjugated through its hydroxyl group directly to the carboxyl group of a glycine residue.

The rejection over the Japanese Patent Application Publication 2-59526 is withdrawn in the absence of a suitable translation.

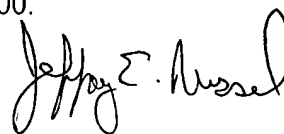
22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1654

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is cursive and stylized, with the first name "Jeffrey" and last name "Russel" clearly distinguishable.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

April 8, 2005